

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

IN RE: BOSTON SCIENTIFIC CORP.,  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

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**THIS DOCUMENT RELATES TO THE FOLLOWING CASE:**

KATRINA BAGWELL, et al.,

Plaintiffs,

v.

BOSTON SCIENTIFIC CORP.,

Defendant.

2:13-CV-24772

**BOSTON SCIENTIFIC CORPORATION’S MOTION FOR SUMMARY JUDGMENT  
AND MEMORANDUM IN SUPPORT**

**INTRODUCTION**

Plaintiffs Katrina Bagwell and Luke Bagwell (“Plaintiffs”) bring this product liability action against Boston Scientific Corporation (“Boston Scientific”) alleging that Boston Scientific’s device—the Solyx Single Incision Sling System—was defective and caused Ms. Bagwell personal injury. Plaintiffs assert causes of action for negligence, strict liability (design defect, manufacturing defect, and failure to warn), breach of express warranty, breach of implied warranty, loss of consortium, fraudulent concealment, and punitive damages. For the reasons discussed below, Boston Scientific is entitled to summary judgment on all of Plaintiffs’ substantive claims.

## **STATEMENT OF FACTS**

1. Plaintiffs Katrina Bagwell and Luke Bagwell are citizens and residents of the State of Colorado. Short Form Complaint (“SFC”) (ECF Doc. 1) at ¶ 4<sup>1</sup>; Plaintiffs’ Fact Sheet (“PFS”) at ¶ I.4.<sup>2</sup>

2. On November 18, 2009, Ms. Bagwell underwent a Solyx Single Incision Sling System (“Solyx”) procedure performed by Dr. Cheryl Cowles at Exemplar Lutheran Health System in Wheatridge, Colorado. SFC at ¶¶ 8, 10-12; PFS at ¶ II.1.

3. The Solyx was implanted to treat Ms. Bagwell’s stress urinary incontinence. PFS at ¶¶ II.1-2.

4. The Solyx is a medical device implanted during surgery by a physician and is available by prescription only. *See* Solyx Directions for Use (“DFU”) at p. 3.<sup>3</sup>

5. The Solyx device was cleared by the Food and Drug Administration in August 2008. *See* FDA Clearance Letter.<sup>4</sup>

6. As a result of the implantation of the Solyx, Ms. Bagwell alleges she has suffered pain, infection, urinary retention, painful intercourse, among other ailments. PFS at ¶ II.6.a.

7. Plaintiff began experiencing issues related to the Solyx in the year following her placement surgery. K. Bagwell Dep. 129:20-130:2<sup>5</sup>; PFS at ¶¶ II.6.a-d.

8. Between placement of the Solyx in November 2009 and August 2010, Ms. Bagwell experienced abdominal pain; inability to lift more than 25 lbs; numbness down her right leg;

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<sup>1</sup> A true and correct copy of Plaintiffs’ SFC is attached as **Exhibit A**.

<sup>2</sup> A true and correct copy of Plaintiffs’ PFS is attached as **Exhibit B**.

<sup>3</sup> A true and correct copy of the Directions for Use for the Solyx device is attached as **Exhibit C**.

<sup>4</sup> A true and correct copy of the Boston Scientific Solyx sling FDA 510k Clearance Letter is attached as **Exhibit D**.

<sup>5</sup> Relevant excerpts of the Deposition of Plaintiff Katrina Bagwell are attached as **Exhibit E**.

urinary urgency, frequency, and retention; vaginal tenderness and pain; dyspareunia; inability to sit or squat without pain; and urinary pain and burning. PFS at ¶¶ II.6.a-d.

9. Ms. Bagwell attributed her alleged injuries to the Solyx device in the Summer of 2011. K. Bagwell Dep. 131:3-132:8.

10. Plaintiffs directly filed this product liability action against Boston Scientific in MDL No. 2326 on October 8, 2013. *See* SFC. They identified the United States District Court for the District of Colorado as the proper venue for this action absent direct filing. SFC at ¶ 5.

11. Ms. Bagwell asserts claims for negligence, strict liability (design defect, manufacturing defect, and failure to warn), breach of express warranty, breach of implied warranty, and fraudulent concealment. SFC at ¶ 13.

12. Plaintiff's husband, Luke Bagwell, also asserts a claim for loss of consortium. SFC at ¶ 13.

### **APPLICABLE LAW**

For implantable medical device cases that originate elsewhere and are directly filed in the MDL, this Court applies the choice-of-law rules of the state in which the plaintiff was implanted with the device. *See Sanchez v. Boston Scientific Corp.*, 2:12-CV-05762, 2014 WL 202787, at \*4 (S.D.W. Va. Jan. 17, 2014); *see also In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2100, 2011 WL 1375011, at \*6 (S.D. Ill. Apr. 12, 2011) (“[T]he better approach is to treat foreign direct filed cases as if they were transferred from a judicial district sitting in the state where the case originated,” which is “the state where the plaintiff purchased and was prescribed the subject drug.”).

Here, Plaintiffs filed this case directly into the MDL and identified the United States District Court for the District of Colorado as the proper venue for this action absent direct filing.

SOF ¶ 10. Plaintiffs are residents of the State of Colorado and Ms. Bagwell had her Solyx device implanted at a medical facility in Wheatridge, Colorado. SOF ¶¶ 1-2. Therefore, for choice-of-law purposes, the United States District Court for the District of Colorado should be considered the originating court. As a result, this Court should apply Colorado’s choice-of-law rules.

Colorado follows the “most significant relationship” test from the Restatement (Second) of Conflict of Laws to determine choice-of-law questions in tort cases. *U.S. Aviation Underwriters, Inc. v. Pilatus Business Aircraft, Ltd.*, 582 F.3d 1131, 1143 (10th Cir. 2009) (citing *AE, Inc. v. Goodyear Tire & Rubber Co.*, 168 P.3d 507, 509-10 (Colo. 2007)). “The law to be applied is ‘the law of the state which, with respect to that issue, has the most significant relationship to the occurrence and to the parties.’” *U.S. Aviation Underwriters*, 582 F.3d at 1143 (quoting Restatement (Second) of Conflict of Laws § 145(1) (1971)). In determining the most significant relationship, courts take the following contacts into account: (a) the place where the injury occurred; (b) the place where the conduct causing the injury occurred; (c) the domicile, residence, nationality, place of incorporation, and place of business of the parties; and (d) the place where the relationship, if any, between the parties is centered. *Id.* at 1143-44 (citing Restatement (Second) of Conflict of Laws § 145(2) (1971)); *Elvig v. Nintendo of Am., Inc.*, 696 F. Supp. 2d 1207, 1210 (D. Colo. 2010).

Plaintiffs are residents of the State of Colorado and the procedure to place the Solyx was performed in Colorado. SOF ¶¶ 1-2. Plaintiffs’ product liability claims are seeking compensation for alleged injuries that occurred in Colorado. SOF ¶¶ 2, 6, 11-12. Accordingly, Colorado has the most significant relationship to this occurrence and to the parties in this matter, and the substantive law of Colorado applies to Plaintiffs’ claims. Further, as Colorado’s limitation periods are

considered substantive law, this Court should apply Colorado's statutes of limitations to Plaintiffs' claims. *See Mountain States Adjustment v. Cooke*, 412 P.3d 819, 823 (Colo. App. 2016).

### **SUMMARY JUDGMENT STANDARD**

Summary judgment is proper when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). Summary judgment "is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to 'secure the just, speedy and inexpensive determination of every action.'" *Celotex*, 477 U.S. at 327 (citations omitted).

Not every factual dispute between the parties will prevent summary judgment. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). Although the Court must review the evidence in the light most favorable to the non-moving party, the non-moving party is required to do more than show some "metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Conclusory allegations or unsupported speculation is insufficient to preclude the granting of a summary judgment motion. *See Felty v. Graves-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987); *Ross v. Commc'ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), *abrogated on other grounds by Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989).

### **ARGUMENT**

#### **I. PLAINTIFFS' CLAIMS ARE BARRED BY THE APPLICABLE STATUTES OF LIMITATIONS**

##### **a. Plaintiffs' personal injury, strict liability, fraudulent concealment, and loss of consortium claims are barred by the relevant two-year statutes of limitations.**

Under Colorado law, claims for breach of warranty governed by the Uniform Commercial Code must be brought within three years after the cause of action accrues. C.R.S. § 13-80-

101(1)(a). Claims for breach of warranty accrue upon the discovery of the breach or on the date when, in the exercise of reasonable diligence, the breach should have been discovered. C.R.S. § 13-80-108(6); *see also Hersch Cos. Inc. v. Highline Village Assocs.*, 30 P.3d 221, 224-25 (Colo. 2001); *Stiff v. BilDen Homes, Inc.*, 88 P.3d 639, 642 (Colo. App. 2003). All other product liability claims against a manufacturer, regardless of the legal theory under which they are brought, are subject to a two-year statute of limitations. C.R.S. § 13-80-106(1); *see also Boyd v. A.O. Smith Harvestore Products, Inc.*, 776 P.2d 1125, 1127 (Colo. App. 1989) (applying product liability statute of limitations to fraud claims). Likewise, a tort action for loss of consortium not arising out of the use or operation of a motor vehicle is also subject to a two-year statute of limitations. C.R.S. § 13-80-102(1)(a).

Colorado follows the “discovery rule” for determining when a cause of action accrues: “[A] cause of action for injury to [a] person . . . shall be considered to accrue on the date both the injury and its cause are known or should have been known by the exercise of reasonable diligence.” C.R.S. § 13-80-108(1). Thus, “[a] claim for relief ‘does not accrue until the plaintiff knows, or should know, in the exercise of reasonable diligence, all material facts essential to show the elements of that cause of action.’” *Miller v. Armstrong World Indus., Inc.*, 817 P.2d 111, 113 (Colo. 1991) (quoting *City of Aurora v. Bechtel Corp.*, 559 F.2d 382, 389 (10th Cir. 1979)).

Ms. Bagwell was implanted with the Solyx on November 18, 2009. SOF ¶ 2. Ms. Bagwell claims she has suffered from a number of ailments due to the implantation of the Solyx, including pain, infection, urinary retention, and painful intercourse. SOF ¶ 6. Ms. Bagwell testified that she attributed her alleged injuries to the Solyx device in the Summer of 2011. SOF ¶ 9. Plaintiffs did not file their Complaint until October 8, 2013. SOF ¶ 10. Because Plaintiffs filed suit against Boston Scientific for damages allegedly caused by the Solyx in October 2013—more than two

years after the “Summer of 2011”—Plaintiffs’ claims against Boston Scientific for negligence, strict liability (design defect, manufacturing defect, and failure to warn), fraudulent concealment, and loss of consortium are barred under Colorado law. Boston Scientific is entitled to summary judgment on these claims.

**b. Plaintiffs’ breach of warranty claims are barred by the applicable three-year statute of limitations.**

Plaintiffs’ claims for breach of warranty are also barred by the applicable three-year statute of limitations. Breach of warranty claims accrue on the date when, in the exercise of reasonable diligence, the breach should have been discovered. *See* C.R.S. § 13-80-108(6).

Ms. Bagwell began experiencing issues related to placement of the Solyx in the year following her surgery in November 2009. SOF ¶ 7. Between placement of the Solyx in November 2009 and August 2010, Ms. Bagwell experienced abdominal pain; inability to lift more than 25 lbs; numbness down her right leg; urinary urgency, frequency, and retention; vaginal tenderness and pain; dyspareunia; inability to sit or squat without pain; and urinary pain and burning. SOF ¶ 8. Plaintiffs did not file this action until October 8, 2013. SOF ¶ 10.

Like the other claims asserted in this lawsuit, Plaintiffs’ claims for breach of warranty are barred by the applicable three-year statute of limitations. Ms. Bagwell claims she experienced myriad symptoms commencing shortly after her surgery to place the Solyx. *See* SOF ¶ 8. As confirmed by Ms. Bagwell’s assertions, it is undisputed that Ms. Bagwell was aware of her claimed injuries no later than August 2010. *Id.* Therefore, Plaintiffs’ warranty claims accrued no later than August 2010. For Plaintiffs to proceed on their claims for breach of warranty, they would have had to file this action by August 2013. Plaintiffs, however, did not file this action until October 2013, more than three years after accrual of Ms. Bagwell’s claims for breach. *See* SOF ¶ 10.

Plaintiffs' breach of warranty claims are barred under Colorado law, and Boston Scientific is entitled to judgment in its favor.

## **II. BOSTON SCIENTIFIC IS ENTITLED TO SUMMARY JUDGMENT ON PLAINTIFFS' STRICT LIABILITY AND NEGLIGENT MANUFACTURING DEFECT CLAIMS**

Should the Court allow Plaintiffs' to maintain their time-barred causes of action, Boston Scientific is still entitled to summary judgment. To prevail on a products claim for strict liability under Colorado law, a plaintiff must prove: (1) the product was in a defective condition unreasonably dangerous to the user or consumer; (2) the product was expected, and did, reach the consumer without substantial change in the condition in which it was sold; (3) the defect cause the plaintiff's injury; (4) the defendant sold the product and is engaged in the business of selling products; and (5) the plaintiff sustained damages. *Barton v. Adams Rental, Inc.*, 938 P.2d 532, 536-37 (Colo. 1997). In a product liability action based on negligence, a plaintiff must prove: (1) the product was in a defective condition unreasonably dangerous; (2) the defect resulted from the defendant's breach of a duty owed to the plaintiff; (3) the defect caused injury to the plaintiff; and (4) the plaintiff suffered damages.

Whether brought as strict liability or negligence, a plaintiff must prove that the subject product was defective and unreasonably dangerous. *Mile Hi Concrete, Inc. v. Matz*, 824 P.2d 198, 205 (Colo. 1992). A product may be found to be "unreasonably dangerous" due to a manufacturing defect, design defect, or failure to warn. *Camacho v. Honda Motor Co. Ltd.*, 741 P.2d 1240, 1247 (Colo. 1987). In a manufacturing defect case, a product is unreasonably dangerous if it was not produced in conformity with the manufacturer's specifications. *Id.*

In this case, Plaintiffs have no evidence—expert or otherwise—to support a theory that the Solyx device in question deviated from its manufacturing specifications or intended design.

Further, Plaintiffs cannot demonstrate that any alleged manufacturing deviation in the Solyx caused Ms. Bagwell's alleged injuries. Plaintiffs cannot satisfy their burden of proof on her strict liability and negligent manufacturing defect claims, and Boston Scientific is entitled to entry of judgment in its favor.

### **III. BOSTON SCIENTIFIC IS ENTITLED TO SUMMARY JUDGMENT ON PLAINTIFFS' BREACH OF WARRANTY CLAIMS**

#### **A. Plaintiffs' claim for breach of express warranty fails for lack of evidence.**

Pursuant to Colorado law, a product liability action for breach of warranty is governed by the Uniform Commercial Code. *Persichini v. Brad Ragan, Inc.*, 735 P.2d 168, 175-766 (Colo. 1987). In accordance with C.R.S. § 4-2-313, express warranties by a seller are created by an "affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." C.R.S. § 4-2-313(1)(a). To prevail on a claim for breach of express warranty, a plaintiff must plead and prove that the seller made an affirmation of fact that was part of the basis of the bargain between the parties. *See Colorado-Ute Elec. Ass'n, Inc. v. Envirotech Corp.*, 524 F. Supp. 1152, 1156 (D. Colo. 1981).

Ms. Bagwell cannot prove she exchanged any communications directly with Boston Scientific regarding the Solyx, whether before or after her surgery. There is neither evidence to indicate the terms of an alleged warranty nor evidence that such terms were expressly made to Ms. Bagwell, thereby inducing her to use the Solyx. *See Duncan v. Board of County Com'rs of Routt County*, 391 P.2d 368, 370-71 (Colo. 1964). Ms. Bagwell cannot identify any affirmation of fact or promise made by Boston Scientific that was part of a "basis of the bargain" between the parties. C.R.S. § 4-2-313(1)(a). Plaintiffs' claim for breach of express warranty fails and Boston Scientific is entitled to summary judgment.

**B. Plaintiffs' claim for breach of implied warranty of merchantability fails for lack of evidence.**

To succeed on a claim for breach of implied warranty of merchantability, a plaintiff must prove: (1) a sale of goods, (2) by a merchant of those goods, and (3) the goods were not of merchantable quality. *See* C.R.S. § 4-2-314. For goods to be “merchantable,” they must be “fit for the ordinary purposes for which [they] are used,” be “adequately contained, packaged, and labeled as the agreement may require,” or “conform to the promises or affirmations of fact made on the container or label[,] if any.” *Id.* at (2)(c), (e)-(f).

Plaintiffs' claim for breach of implied warranty of merchantability fails. There is no evidence to suggest the Solyx was not fit to treat Ms. Bagwell's stress urinary incontinence, or that it failed to do so. In addition, there is no evidence that the Solyx implanted in Ms. Bagwell was not packaged appropriately for use prior to her procedure. Further, Ms. Bagwell has not alleged that her Solyx did not conform to the affirmations of fact that were provided on its container or label. Plaintiffs have failed to satisfy the evidentiary requirements necessary to proceed against Boston Scientific on a claim for breach of implied warranty of merchantability. Therefore, Boston Scientific is entitled to entry of judgment in its favor on Plaintiffs' claim.

**C. Plaintiffs' claim for breach of implied warranty of fitness for a particular purpose fails for lack of evidence.**

To prevail on a claim for breach of implied warranty of fitness for a particular purpose, a plaintiff must demonstrate that: (a) the product was to be used by the buyer for a particular purpose different from its ordinary purpose; (b) the seller knew of the buyer's particular purpose; (c) the seller knew that the buyer was relying on the seller's skill to provide a product that would satisfy the particular purpose; and (d) the buyer in fact relied on that skill. *Fiberglass Component Production, Inc. v. Reichhold Chemicals, Inc.*, 983 F. Supp. 948, 956 (D. Colo. 1997) (citing

C.R.S. § 4-2-315) (quotations omitted). A “particular purpose” is a “specific use by the buyer which is peculiar to the nature of his business,” and “differs from the ordinary purpose for which the goods are used.” *Fiberglass*, 983 F. Supp. at 956.

Plaintiffs’ claim for breach of implied warranty of fitness for a particular purpose fails for lack of evidence. There is no evidence in the record to suggest Ms. Bagwell, in obtaining treatment through use of the Solyx, intended to use the Solyx for anything but its intended purpose—to treat stress urinary incontinence. Ms. Bagwell has pleaded not a particular purpose for obtaining the Solyx, outside of its ordinary use, and there is no evidence to support such an allegation. Plaintiffs cannot support a claim for breach of implied warranty of fitness for a particular purpose, and Boston Scientific is entitled to summary judgment in its favor.

#### **IV. BOSTON SCIENTIFIC IS ENTITLED TO SUMMARY JUDGMENT ON PLAINTIFFS’ CLAIM FOR FRAUDULENT CONCEALMENT**

Plaintiffs’ SFC and the Master Long Form Complaint demonstrate that Plaintiffs’ fraudulent concealment allegations are meant only to defeat a statute of limitations defense and do not constitute a standalone claim for fraudulent concealment. *See* SFC at ¶ 13; Master Complaint at ¶¶ 88-92<sup>6</sup>; *see also Mubita v. Boston Scientific Corp.*, No. 2:13-cv-11955, 2015 WL 5838515, at \*5 (S.D.W. Va. Oct. 5, 2015) (granting summary judgment to Boston Scientific on fraudulent concealment claim where pleadings revealed claim was asserted only as “a safeguard to toll the statute of limitations”); *Kilgore v. Boston Scientific Corp.*, No. 2:13-cv-09171, 2015 WL 5838513, at \*6 (S.D.W. Va. Oct. 5, 2015) (same). The Master Complaint does not discuss fraudulent concealment independent of the statute of limitations. Boston Scientific is entitled to summary judgment on this claim.

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<sup>6</sup> A true and correct copy of the Master Long Form Complaint is attached as **Exhibit F**.

However, to the extent Plaintiff does intend to pursue fraudulent concealment as a standalone claim, summary judgment should be entered in favor of Boston Scientific. The elements of a fraudulent concealment claim in Colorado include:

(1) the concealment of a material existing fact that in equity and good conscience should be disclosed; (2) knowledge on the part of the party against whom the claim is asserted that such a fact is being concealed; (3) ignorance of that fact on the part of the one from whom the fact is concealed; (4) the intention that the concealment be acted upon; and (5) action on the concealment resulting in damages.

*BP America Production Co. v. Patterson*, 263 P.3d 103, 109 (Colo. 2011) (citing *First Interstate Bank of Fort Collins, N.A. v. Piper Aircraft Corp.*, 744 P.2d 1197, 1200 (Colo. 1987)).

Plaintiffs cannot establish the elements of a fraudulent concealment claim. The record is devoid of any evidence that Boston Scientific knowingly concealed a material fact regarding the Solyx that should have been disclosed. Further, there is no evidence that any action by Ms. Bagwell or her implanting physician was based on the concealment of a fact, which ultimately resulted in damages. Because Ms. Bagwell cannot establish the elements of a fraudulent concealment cause of action, summary judgment should be entered in favor of Boston Scientific.

#### **V. PLAINTIFFS' LOSS OF CONSORTIUM CLAIM FAILS**

A loss of consortium claim is derivative in nature and a spouse may only recover if there is an underlying cause of action against the same defendant. *Lee v. Colo. Dept. of Health*, 718 P.2d 221, 232 (Colo. 1986). Because summary judgment is appropriate as to all of Ms. Bagwell's substantive claims, summary judgment is also warranted as to her husband's claim for loss of consortium.

#### **CONCLUSION**

For all of the foregoing reasons, Boston Scientific respectfully requests this Court grant its Motion for Summary Judgment on Plaintiffs' claims against it.

Dated: May 13, 2019.

Respectfully Submitted,

s/ Eric Anielak

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 13, 2019, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: /s/ Eric Anielak  
Attorney